Roethig, Hans

From: Osborne, Kevin (PMMC Legal)
Sent: Thursday, November 07, 2002 10:00 AM
To: Adams, Candace R.; Roethig, Hans
Cc: 'Robert_Conley@aporter.com'
Subject: RE: Draft Surveillance Plan

Candace and Hans:

Further to our call this AM, I enclose general overview comments and advice from Rob which we discussed. In addition, I will be fwding. to Candace specific comments and advice from the both of us to the drafts.

Please let me know if you'd like to discuss further.

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(1) The IOM Report ideal surveillance system discussed in Chapter 6 envisions a comprehensive surveillance system conducted primarily by government agencies. Regulatory Principle 6 would give a regulatory agency authority to require postmarketing surveillance and epidemiological studies from manufacturers of products with reduced-risk claims. I understand that PM wants to conduct surveillance and epi studies for products with reduced-exposure claims in addition to any products with reduced-risk claims. In the draft best practices, however, we made sure that there were caveats about how no single government agency, much less a single company, could implement all aspects of the IOM ideal surveillance system. I think similar caveats need to appear in these materials. The matching up of questions and IOM recommendations makes it seem that PM is taking on the entire surveillance system. While part of the surveillance may entail comparisons with other products, I think the plan needs to be clear and explicit that it is attempting to address only limited aspects of surveillance and is focused primarily on PM products and not the nationwide tobacco market and not all aspects of the IOM ideal system.

(2) The materials frequently refer to monitoring/assessing the impact or accuracy of "reduced exposure claims." I don't think these articulations are quite right. The surveillance plan is really looking at the impact of the availability of the product itself -- and not so much on the specific claims. For example, the reduced exposure claims in the materials are based on per cigarette comparisons, and the surveillance plan at this point is not looking at per cigarette exposure reductions (although I understand those types of actual studies where Accord smokers are brought back for measurements may be conducted further down the road). There will be calculations of total exposure to some constituents, but I don't think there are any claims made about that -- the product materials instead say that the reductions depend on not compensating by smoking more, etc. The surveillance is looking to see whether that sort of compensation happens. This is a broader-based population issue that does not directly implicate the accuracy of the marketing claims. In fact, the initial surveillance cannot really assess the accuracy of the reduced exposure claims because it is estimating exposure based on the same methodology used to support the claim -- only the later studies will be able to determine exposure on a per cigarette basis in a real world environment.

(3) The plan refers primarily to the BRFSS survey, while the IOM Report lists several different surveys. Why was the BRFSS chosen as opposed to, say, the NHIS? How similar will the data be?

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(4) The descriptions of Accord need to be consistent with the marketing materials and appropriately caveated. Specifically, I'm not sure that "results in a significant reduction of exposure to smoke constituents identified as harmful" is correct -- I thought the word "certain" appeared in front of "smoke constituents" or that the statement was otherwise caveated.

(5) I'm not sure how the information from consumer complaints fits in -- how it will be compiled, analyzed, etc.

(6) Will the questionnaires be validated? One issue that always comes up with these sort of things is whether the survey instrument really measures what it is supposed to be measuring and does so consistently and reliably. Some questions may be identical to questions that are already part of other validated surveys, but others are clearly not. An external organization may be able to do this, but it probably needs to be done and probably should be addressed in the surveillance plan (e.g., include that an external organization will validate the survey instruments).

(7) Both the baseline and follow-up questionnaires ask whether the person currently smokes Accord and if the answer is "no," then no additional questions are asked. What is the rationale for that? In terms of assessing the population use of Accord, it may be relevant to know whether, for example, someone who just initiated smoking with Accord is now smoking other products or has abandoned smoking entirely. On the other side of the equation, if someone used Accord as a step-down or bridge to stop smoking entirely, that information would not be captured either -- the follow-up doesn't ask about it.

(8) Re the public reports, I think it will be important to make sure no inappropriate confidential or commercially important information is inadvertently included -- in other words, that the contents of the report are carefully considered and described accurately in these documents.

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